Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 28 has been amended to incorporate the subject matter of claim 32, as a result of which claim 32 has been cancelled.

In view of the amendment to claim 28, claim 31 has been amended to indicate that the composition further comprises at least one water-soluble or water-dispersible polymer as recited in claim 31, while deleting hydroxypropylmethyl cellulose and polyvinyl pyrrolidone, which are now essential components in amended claim 28.

The rejection of claims 10-23 under 35 U.S.C. §101, and the corresponding rejection of these claims under the second paragraph of 35 U.S.C. §112, are respectfully traversed.

The Examiner takes the position that these claims embrace both a product and a process of using it. Applicants respectfully submit that this is not correct. The expression "said film effects . . . when adhered to said oral cavity" does not recite a process of using the film, but rather, recites a property of the film. Further attention in this regard is directed to MPEP 2173.05(g), indicating that there is nothing inherently wrong with defining some part of an invention in functional terms, by what it does, rather than what it is, i.e. a functional limitation is often used to define a particular capability or purpose that is served by the recited element.

In view of these considerations, there is no doubt that independent claim 10, and thus dependent claims 11-23, relate exclusively to a composition of matter, rather than being directed to subject matter belonging to more than one statutory class of invention. Accordingly, the rejection of the claims under 35 U.S.C. §101 and the second paragraph of 35 U.S.C. §112 should be withdrawn.

The rejection of claims 10-23 under the first paragraph of 35 U.S.C. §112 is respectfully traversed.

The Examiner argues that the limitation "said film effects the transmucosal delivery" previously inserted in claim 10 is not supported by the specification. The Examiner states that the specification does support delivering the compositions to the

mucosa but not necessarily across the mucosal membrane. However, the disclosure at the beginning of the paragraph bridging pages 5 and 6 of the specification (previously relied upon for support of this limitation) refers to delivery of active ingredients **via** the mucous membranes of a patient. The expression "via" generally means "by a route passing through" (quoted from Webster's New World Dictionary). Hence, it is clear that the wording "delivery . . . via the mucous membranes" indicates that the active substances are delivered across these membranes. This follows also from the whole context of the paragraph bridging pages 5-6, where it is explained that delivering the active substances "via" the mucous membranes is of particular advantage in such cases where a therapeutic agent is only poorly absorbed due to solubility limitations, or is subject to degradation in the gastro-intestinal tract (it administered by a conventional administration form such as a pill or capsule), or undergoes extensive metabolism before arriving at its target organ or tissues. By transmucosal administration using the presently claimed films, the active substances enter the circulatory system directly via the mucous membranes of the oral cavity, thus avoiding the drawbacks associated with conventional oral administration forms.

The disclosure of "delivery . . . via the mucous membranes" further implies that the delivered substances must be therapeutic agents that have systemic (rather than local) activity. In the case of therapeutic substances that are administered only topically and which act only locally, transmucosal delivery generally has to be avoided to prevent any potential negative side effects that may result when such therapeutic substances would enter the circulatory system. Accordingly, the paragraph bridging pages 5-6 of the present specification recites classes of drugs that generally have systemic rather than local action. The skilled person will be able to distinguish between drugs that act only locally in the oral cavity, and drugs that have systemic action and that must enter the human body (as, in the present case, by transmucosal delivery) before they can become therapeutically active at their respective target organs or tissues.

Applicants thus respectfully submit that the claim language referred to by the Examiner is clearly supported by the specification as filed, and thus, the rejection of the claims under the first paragraph of 35 U.S.C. §112 should be withdrawn.

The patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 10 and 13 under 35 U.S.C. §103(a) as being unpatentable over Schmidt (US 5,354,551) is respectfully traversed.

The Examiner appears to argue that films claimed in present claim 10 are encompassed by the preparations disclosed by Schmidt and that, therefore, the prior art preparations are assumed to be also mucoadhesive and suitable for effecting transmucosal delivery.

Although the presently claimed films and the preparations disclosed by Schmidt both may contain water-soluble, film-forming polymers such as "natural or synthetic resins or gums" (Schmidt, col. 2, lines 28-39), this does not necessarily imply or suggest that the preparations taught by Schmidt are also mucoadhesive. This prior art document relates to "oral and dental hygiene preparations", and these preparations generally contain abrasives which are required for efficient cleaning action (col. 2, lines 4-9; col. 3, the Example; and claim 1). Abrasives are present in the form of abrasive particles, and due to the presence of such particles, the preparations described by Schmidt will tend to have a rough surface structure which will interfere with surface adhesion, As noted previously, Schmidt does not teach the tooth care preparations to be mucoadhesive, and from the whole context of Schmidt's teaching it is clear that mucoadhesiveness would be disadvantageous as it would cause the preparation (or pieces of this preparation) to adhere to the buccal mucosa where it would no longer be available for dental cleansing.

On the other hand, claim 10 (and claim 13) is directed to a mucoadhesive film, wherein the film is able to be adhered to an oral cavity. Since, as indicated above, the abrasives will interfere with surface adhesion, and thus the film would not be able to be adhered to the oral cavity, it is apparent that the film of the present invention does not contain abrasives, thus being clearly distinguished from the Schmidt preparation.

Furthermore, in general the term "mouth and tooth care preparation" used by Schmidt clearly indicates that this preparation, due to its composition and physical properties, is specifically adapted to be used for this purpose, similarly to a toothpaste (see col. 1). The description "mouth and tooth care preparation" is not merely an

"intended use", but it rather reflects the chemical composition and the properties of the preparation. Likewise, the description "film formed from a mucoadhesive composition ... said firm effects the transmucosal delivery..." is not merely an intended use, but further defines the properties of the claimed composition. Schmidt teaches that the "mouth and tooth care preparation" is similar to a toothpaste, although it is formulated differently. However, it is quite clear that a toothpaste (or a composition resembling a toothpaste) has nothing in common with a mucoadhesive drug delivery device as presently claimed.

Regarding the presence of one or more pharmaceutically active agents, it was explained above that Schmidt fails to teach incorporating any active agents that are capable of being absorbed transmucosally and that have systemic action in the human body. From the whole teaching of Schmidt it is absolutely clear that the "antibacterial agents" mentioned in col. 2 are added for the sole purpose of improving oral or dental hygiene, and that these agents are not selected from the group of pharmaceutically active agents having systemic action.

In this connection, the Examiner has additionally referred to DE 196 15 820 Al (Specht). However, Applicants take the position that this reference is not available as prior art against the present invention, because according to the translation provided by the Examiner, the publication date of the reference is October 9, 1997, which is after the filing date of August 1, 1997 for the first-filed parent application of the present application. The Examiner uses the reference to support the argument that toothpastes are in fact used to deliver substances through the oral mucosa, and therefore having mucoadhesive polymers in toothpaste is advantageous. But such knowledge was not available to the art-skilled until after the effective filing date of the present application, and therefore cannot be used to reject the claims.

In addition, the dental care products disclosed by Specht are not described as being mucoadhesive. Therefore, the presently claimed films would not have been obvious even when combining the teachings of both references. The preparations taught by Schmidt or Specht are equally unsuitable for transmucosal and systemic delivery of pharmaceutically active agents since they release the incorporated active substances during toothbrushing, and an undefined amount of active substance is lost when the user or patient rinses his/her mouth afterwards. Therefore, these prior art preparations are

obviously not suitable for transmucosally delivering defined doses of active substance to a patient.

Accordingly, Applicants take the position that the subject matter of claims 10 and 13 is clearly patentable over Schmidt (and Specht).

The rejection of claim 19 under 35 U.S.C. §103(a) as being unpatentable over Schmidt in view of Story et al. (US 4,944,949), as well as the rejection of claims 11-12, 14-18 and 21-23 under 35 U.S.C. §103(a) as being unpatentable over Schmidt in view of Acharya (US 5,686,094), are respectfully traversed.

Since all of these rejected claims are directly or indirectly dependent on claim 10, the subject matter of these claims is patentable over the applied references for the same reason that claim 10 is patentable over Schmidt, as discussed above. Neither Story et al. nor Acharya suggests anything which would lead one of ordinary skill in the art to modify the teachings of Schmidt in a manner which would suggest the subject matter of claim 10.

The rejection of claims 24-27 and 32 under 35 U.S.C. §103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Acharya is respectfully traversed.

Initially, the first sentence of item 4 on page 6 of the Office Action includes claim 32 (along with claims 24-27) in this rejection under 35 U.S.C. §103(a), but the next sentence indicates that the rejection is withdrawn in regards to claim 32. No separate comments with regard to the subject matter of claim 32 are set forth in the item 4 rejection. It is therefore Applicants' understanding that the Examiner is not rejecting claim 32 based on Keith et al. in view of Acharya.

Independent claim 24 pertains to a monolayer film comprising, as pharmaceutically active agent, nicotine (or a salt thereof) in combination with flavoring agents selected from menthol and mint flavor, and with a sweetener selected from aspartame and sorbitol, and with tartaric acid as a flavor enhancing agent.

Keith et al. relates to buccal dosage forms that may have nicotine incorporated therein. As regards the additional ingredients recited in present claim 24 (flavoring agents, etc.), the Examiner has referred to Keith, col. 4, lines 28-33, where it is stated that

additional ingredients may be incorporated in the matrix to provide desirable physical properties or modify the properties of the matrix. However, the unpleasant taste of nicotine is not a property of the matrix (as suggested by the Examiner) but rather a property of this active substance itself. From the passage in col. 4, lines 28-33, it clearly follows that the term "properties of the matrix" refers to properties such as rigidity or resilience which may be modified by adding plasticizers, but not to properties inherent to the active substance. On page 6, last paragraph, of the Office Action, the Examiner states that Keith et al. "discloses polyvinylpyrrolidone acts as an odor masking substance", but no support for this statement can be found in this reference. According to Keith et al., col. 4, first paragraph, polyvinylpyrrolidone is considered as a suitable matrix polymer.

While Keith et al. teach nicotine, this reference fails to teach a combination of ingredients (as defined in present claim 24) for suppressing the unpleasant taste of this active substance. Acharya mentions various substances that are suitable as taste-fresheners or flavorants, but fails to teach which substances or combination of substances might be suitable to be used in combination with nicotine. Therefore, since each of Keith et al. and Acharya discloses a whole range of different active substances, and since Acharya discloses taste-fresheners or flavorants without teaching any specific combinations of unpleasantly tasting active substances and taste-fresheners or flavorants, it was not obvious to one of ordinary skill in the art to combine nicotine (or a salt thereof) with flavoring agents selected from menthol and mint flavor, and with a sweetener selected from aspartame and sorbitol, and with tartaric acid as a flavor enhancing agent. This specific combination of active substance and taste-modifying substances was not rendered obvious by the cited prior art documents.

The rejection of claims 20 and 36-37 under 35 U.S.C. §103(a) as being unpatentable over Keith et al. in view of Story et al. is respectfully traversed.

Initially, as with the rejection in item 4 discussed above, this rejection in item 5 indicates that it is withdrawn in regards to claims 36-37. Therefore, it is Applicants' understanding that claims 36-37 are not included in this rejection.

The comments set forth above concerning the Keith et al. reference are equally applicable to this rejection, as regards the combination of nicotine with flavoring agents and sweeteners (see present claims 10 and 20). Further, Keith et al. fail to teach the

presence of "at least two surfactants" (claims 10, 20). With respect to surfactants, the Examiner has referred to Story et al. However, this reference specifically teaches the use of surfactants for forming micelles together with NSAIDs. These drugs are chemically different from nicotine, and the skilled person would not have considered combining the surfactants (which according to Story et al. are used for the specific purpose of forming micelles with NSAIDs) with nicotine.

Again, the passage from Keith et al. (col. 4, lines 28-33) relating to additional ingredients cannot serve as motivation for adding surfactants as taught by Story et al. Keith et al. relates to additional ingredients for modifying the properties of the matrix. According to Story et al., the incorporation of surfactants (in combination with NSAIDs) has the effect of micelle formation. However, micelle formation takes place only in aqueous solution and not in the solid matrix of the drug composition (see col. 4, lines 39-48). Story et al. also consider liquid compositions in which the NSAID is already present in the form of micelles. However, a liquid composition cannot be said to have a "matrix" as required by Keith et al. (col. 4, lines 28-33). Therefore, there is no basis for combining the teachings of Keith et al. and Story et al.

The rejection of claims 28-29, 31, 33-35 and 38-40 under 35 U.S.C. §103(a) as being unpatentable over Keith et al. in view of Inoue et al. (US 4,772,470) is respectfully traversed.

Applicants respectfully submit that this rejection has been rendered moot, since the subject matter of claim 32, which is not subject to this rejection, has been incorporated into claim 28, the only independent claim subject to this rejection.

The rejection of claim 30 under 35 U.S.C. §103(a) as being unpatentable over Keith et al. in view of Inoue et al. and further in view of Stanley et al. (US 5,783,207), as well as the rejection of claims 36-37 under 35 U.S.C. §103(a) as being unpatentable over Keith et al. in view of Inoue et al. and further in view of Story et al., are respectfully traversed.

Claims 30 and 36-37 are dependent on claim 28, which is patentable over Keith et al. in view of Inoue et al. for the reasons discussed above. For the same reasons, claims 30 and 36-37 are patentable over this combination of references taken with either Stanley et al. or Story et al. Neither Stanley et al. nor Story et al. disclose anything which would

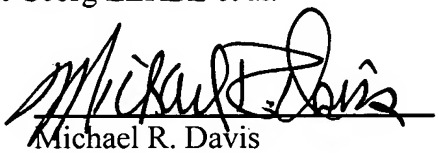
lead one of ordinary skill in the art to modify the teachings of Keith et al. and Inoue et al. in a manner which would suggest the subject matter of claim 28.

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

Horst Georg ZERBE et al.

By: 

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